UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRASSICA PROTECTION PRODUCTS LLC and THE JOHNS HOPKINS UNIVERSITY,

Plaintiffs,

-against-

CAUDILL SEED & WAREHOUSE CO., INC. d/b/a CAUDILL SEED CO.,

Defendant.

07 Civ. 7844 (SAS)

Filed Electronically

PLAINTIFFS' MEMORANDUM OF LAW REGARDING CLAIM CONSTRUCTION

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Pursuant to Paragraph (3)(h) of the November 14, 2007 Scheduling Order, Plaintiffs Brassica Protection Products LLC ("Brassica") and The Johns Hopkins University ("Johns Hopkins"), by and through their undersigned counsel, Bingham McCutchen LLP, hereby submit their Memorandum of Law Regarding Claim Construction.

Introduction

Following more than 20 years of research led by Dr. Paul Talalay, scientists at Johns Hopkins identified components in broccoli and other cruciferous vegetables that boost the body's enzyme systems, detoxifying carcinogens before they damage cells. They also found that sprouts and seeds of cruciferous plants contain much more of these protective compounds than do mature plants.[1] Beginning in 1998, patents relating to this discovery were issued to Johns Hopkins and the scientists who made this discovery. These patent rights have been exclusively licensed to Brassica. *Amended Complaint,* ¶¶ *7-12.*

Brassica develops and promotes chemoprotective products, including dietary supplements based on the extraction and processing of glucosinolates or isothiocyanates from cruciferous seeds and/or sprouts. *Talalay Decl.*, ¶ *2*. The five patents asserted in this action are directed to cruciferous food products that deliver compounds, called "Phase 2" enzyme inducers, which detoxify carcinogens. Ingesting those inducers, or their precursors, confers chemoprotection against cancer.

In December, 2004 Brassica entered into a non-exclusive sublicense agreement (the "Agreement") with defendant Caudill Seed & Warehouse Co., Inc. ("Caudill"), a Kentucky company. The Agreement permitted Caudill to produce, manufacture, distribute, and sell in the United States the licensed products, including "extracted or purified glucosinolate or

[1] Declaration of Antony Talalay, executed November 27, 2007, and filed with the Court in opposition to Defendant's Motion to Transfer, Stay or Dismiss ("Talalay Decl."), ¶ 3.

isothiocyanate to be included as in ingredient in a capsule, tablet, pill or similar form...." *Agreement (Amended Complaint, Exh. F), §§ 2.1, 1.17.* Due to Caudill's failure to meet its contractual obligations, Brassica terminated the Agreement following notice and an opportunity to cure, effective July 21, 2007. *Amended Complaint, ¶¶ 27-34.*

Notwithstanding the termination of the Agreement, Caudill continues to produce, manufacture, distribute, sell, and offer for sale within the United States the exact same products that it did under the Agreement, which are covered by the asserted patents. Caudill's production methods also are unchanged. *See Amended Complaint, ¶¶ 39-40.* Moreover, although Caudill now opportunistically asserts claim constructions that would severely restrict the scope of the patents, prior to this litigation, Caudill freely used (and understood) terms that broadly described the products it sold, and continues to sell, in a manner that brings them squarely within the claims of the asserted patents. Caudill's attempt now to avoid findings of infringement through unsupportable proposed constructions of claim terms must be viewed in this context.

I. FACTUAL BACKGROUND

A. The Asserted Patents

Plaintiffs allege infringement of five patents: U.S. Patent No. 5,725,895 ("the '895 patent"); U.S. Patent No. 5,968,567 ("the '567 patent"); U.S. Patent No. 6,177,122 ("the '122 patent"); U.S. Patent No. 6,242,018 ("the '018 patent"); and U.S. Patent No. 7,303,770 ("the '770 patent"). *Amended Complaint, Exhs. A-E.*[2] The '567 patent is a continuation of the original '895 patent. The '122, '018, and '770 patents are divisionals of the '567 patent. Accordingly, they share a common specification.

[2] In its answer and counterclaims, Defendant seeks, *inter alia*, a declaration that four other Johns Hopkins patents are invalid or unenforceable. These other patents are not the subject of the claim construction proceeding in this action.

The asserted patents claim a "Method of Preparing a Food Product From Cruciferous Seeds" ('895 patent), a "Method of Preparing a Food Product From Cruciferous Sprouts," ('567 patent), and "Cancer Chemoprotective Food Products" ('122, '018, and '770 patents). *See Exhs. 1A-5A.* The common specification among the asserted patents explains the basic nature of the claimed inventions. The specification observes that "diet plays a large role in controlling the risk of developing cancers and that increased consumption of fruits and vegetables reduces cancer incidence in humans." *Exh. 1-A (the '895 patent), col. 1, ll. 28-32.* The specification further explains that substances helpful against cancer, "chemoprotectors," induce activities of Phase 2 enzymes. *See Exh. 1-A (the '895 patent), col. 1, ll. 36-65.*

Phase 2 enzymes have a chemoprotective effect against cancer because they are part of the human body's mechanism for detoxifying potential carcinogens. *Exh. 1-A (the '895 patent), col. 1, ll. 28-34.* Accordingly, the patents are directed to "the production and consumption of foods" that contain chemoprotective compounds that can be used to reduce the susceptibility of mammals to carcinogenic agents. *See Exh. 1-A (the '895 patent), col. 1, l. 66-col. 2, l. 7.*

Thus, an express goal of the claimed inventions is "to provide food products and food additives that are rich in cancer chemoprotective compounds." *Exh. 1-A (the '895 patent), col. 2, ll. 37-39.* To that end, the inventions employ a dietary approach to "provide food products which contain substantial quantities of Phase 2 enzyme-inducers and are essentially free of Phase 1 enzyme-inducers." *Exh. 1-A (the '895 patent), col. 2, ll. 40-43.* In other words, the goal of the inventions is to provide chemoprotective Phase 2 enzyme inducers, which can be incorporated into food products and consumed for their cancer-preventing properties.

The particular chemoprotective compounds discussed in the patents are isothiocyanates and glucosinolates. *Exh. 1-A (the '895 patent), col. 6, l. 65-col. 7, l. 3; col. 8, ll. 14-18.*

Isothiocyanates are themselves Phase 2 enzyme inducers. *Exh. 1-A (the '895 patent), col. 7, ll. 2-3*. Glucosinolates are converted by the enzyme myrosinase into isothiocyanates. *Exh. 1-A (the '895 patent), col. 6, l. 65-col. 7, l. 1*.

B. The Asserted Claims

Plaintiffs assert that Defendant is infringing Claims 14 and 15 of the '895 patent; Claims 9, 16, and 18 of the '567 patent; Claims 1, 2, 5, 6, 7, 8, 9, 10, and 12 of the '122 patent; Claims 1 and 2 of the '018 patent; and Claims 10, 13, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, and 26 of the '770 patent.[3]

The asserted claims fall into three categories: (1) methods of preparing food products (*i.e.*, Claims 14 and 15 of the '895 patent; Claims 9, 16, and 18 of the '567 patent; Claims 1 and 2 of the '018 patent; and Claims 10, 13, 15-24, and 26 of the '770 patent); (2) crucifer seed extracts (*i.e.*, Claims 1, 2, and 5 of the '122 patent); and (3) food products containing either crucifer seed extracts (*i.e.*, Claims 6, 7, 8, 9, and 10 of the '122 patent), or a source of glucosinolates or isothiocyanates (*i.e.*, Claim 12 of the '122 patent). While directed to different categories of subject matter, all of Plaintiffs' asserted claims share the inventors' goal – to provide chemoprotective Phase 2 enzyme inducers using a dietary approach.

C. The Claim Terms at Issue

Only two claim terms require construction: **"extract"** and **"food product."** These terms are prevalent throughout the asserted claims. Indeed, at least one of these terms appears in each of the asserted claims.

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[3] In prior unrelated litigation, the Court of Appeals for the Federal Circuit found several of the claims of the '895 and '567 patents to be invalid. Those claims are not asserted here. The Court also construed two claim terms from the '895 and '567 patents: "rich in glucosinolates" and "high Phase 2 enzyme-inducing potential." Similarly, these claim terms are not at issue here. *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002).

Plaintiffs propose that the claim term **"extract"** should be construed to mean:

> **the substance containing beneficial amounts of Phase II enzyme inducers and/or their precursors that results from manipulation of one or more of cruciferous sprouts, seeds, plants, and/or plant parts, where the manipulation causes the separation of component fractions of the cruciferous sprouts, seeds, plants, and/or plant parts.**

Plaintiffs propose that the claim term **"food product"** should be construed to mean:

> **any ingestible substance containing beneficial amounts of Phase 2 enzyme inducers and/or their precursors.**

These proposed constructions are consistent with the intrinsic evidence: the claim language, the inventors' description of their inventions in the patents' specifications, and the prosecution histories of the patents. To the extent extrinsic evidence is needed, Plaintiffs offer the opinion of a qualified expert, Edward M. Sybert, who has extensive experience in the field of the claimed inventions. Mr. Sybert conducted a detailed analysis and his conclusions support Plaintiffs' proposed constructions.

By contrast, Defendant offers unsupportable, narrow constructions that ignore the purpose of the inventions, nullify the inventors' description of the inventions, and lead to absurd results. Indeed, Defendant's own use of the terms prior to this litigation refutes the constructions it now proposes. Nor are Defendant's proposed constructions supported by qualified expert testimony. Defendant's purported expert, Dr. Ziegler, is at most an expert on chocolate with an engineering background ill-suited to the inventions claimed by the asserted patents. Moreover, Dr. Ziegler offered an opinion on only one claim term – "extract" – and focused on only one patent. He spent just a few hours to reach his opinion and did not bother to review the relevant prosecution histories or to take into account the object of the inventions at hand. Dr. Ziegler's conclusions should not be considered as in any way helpful to the Court.

Finally, Defendant unnecessarily asks the Court to construe an additional *eighteen* claim terms. Once "extract" and "food product" are construed, however, the meaning of each of the additional terms proposed by Defendant is readily apparent to a person of skill in the art, as "little more than the application of the widely accepted meaning of commonly understood words" is all that is then necessary. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

II. LEGAL DISCUSSION

A. Plaintiffs' Constructions Follow the Tenets of Claim Construction

In arriving at its proposed constructions, Plaintiffs adhere to the tenets of claim construction mandated by the Federal Circuit. Of primary importance in a claim construction analysis is the language of the claims themselves, which defines the legal scope of the invention and defines what the patentees may exclude others from doing. *See Phillips*, 415 F.3d at 1312; *see also Markman v. Westview Instruments*, 52 F.3d 967, 999 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1960). Plaintiffs' analysis begins with the claims and properly considers the claims to be of primary importance. *Phillips*, 415 F.3d at 1312.

Plaintiffs' proposed constructions also properly rest on the meanings afforded to the claim terms at issue by the patents' common specification. *Phillips*, 415 F.3d at 1313, 1315 ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification;" the patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.").

The prosecution history of the asserted patents is the final element of intrinsic evidence in a claims construction analysis. *See Phillips*, 415 F.3d at 1317. In this case, however, nothing in

the prosecution histories of the asserted patents conflicts with what is conveyed by the claims and specifications regarding the meaning of "extract" and "food product."

Finally, extrinsic evidence supports Plaintiffs' proposed constructions. Such evidence "'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.3d at 980). While it may be helpful, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). Moreover, extrinsic evidence that is "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" should be discounted. *Phillips*, 415 F.3d at 1318.

Expert testimony may be especially useful to the Court in connection with claim construction, including testimony regarding the technology, explaining how the invention works, ensuring that the Court's understanding of the technical aspects of the invention is consistent with that of a person of skill in the art, and establishing that a particular term has a particular meaning in the pertinent field. *Phillips*, 415 F.3d at 1318 (citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308-09 (Fed. Cir. 1999); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)).

The "construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Because Plaintiffs' proposed constructions "stay true" to the claim language and naturally align with the description of the inventions, they should be adopted by this Court.

B. "Extract"

The goal of the claimed inventions is to provide chemoprotective Phase 2 enzyme inducers using a dietary approach. Accordingly, each claimed "extract" must provide the beneficial Phase 2 enzymes and/or their precursors. Thus, Plaintiffs propose that the claim term **"extract"** should be construed to mean:

> **the substance containing beneficial amounts of Phase II enzyme inducers and/or their precursors that results from manipulation of one or more of cruciferous sprouts, seeds, plants, and/or plant parts, where the manipulation causes the separation of component fractions of the cruciferous sprouts, seeds, plants, and/or plant parts.**

1. The Asserted Claims Language

Plaintiffs' proposed construction is supported by the language of the claims. The term "extract" and variants thereof (*i.e.*, "extracting," "extracted") are found in Claims 9, 16, and 18 of the '567 patent; Claim 15 of the '895 patent; Claims 1, 2, 5-10, and 12 of the '122 patent; and Claims 10, 13, 15-24 and 26 of the '770 patent.[4]

Claim 18 of the '567 patent recites: "An extract prepared according to the method of any one of claims 9, 16, or 17." *Exh. 2A (the '567 patent), col. 22, ll. 60-61.* Claim 9 of the '567 patent, in turn, is directed to "A method of preparing a human food product" by:

> [1] "extracting glucosinolates and isothiocyanates from cruciferous sprouts rich in glucosinolates . . . or from cruciferous seeds, or a combination thereof, with a non-toxic solvent,
>
> [2] "removing the extracted sprouts, seeds, or a combination thereof from said solvent and,
>
> [3] "recovering the extracted glucosinolates and isothiocyanates**.**"

Exh. 2A (the '567 patent), col. 22, ll. 22-32.

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[4] *See Exh. 2A (the '567 patent), col. 22, ll. 22-33, 53-55, 60-61; Exh. 1A (the '895 patent), col. 22, ll. 48-58; Exh. 3A (the '122 patent), col. 21, l. 55-col. 22, l. 34; Exh. 5A (the '770 patent), col. 22, ll. 37-45, 50-51, 54-67, col. 23, l. 1-col. 24, ll. 4, col. 24, l. 7-8.*

Thus, reading Claims 9 and 18 of the '567 patent together, the claimed extract plainly is produced by a process which begins with cruciferous sprouts and/or seeds as a starting material. That starting material is rich in cancer-protective glucosinolates and isothiocyanates. The starting material is manipulated by exposing it to a non-toxic solvent. Following exposure to the solvent, the extracted sprouts and/or or seeds are removed from the solvent, resulting in a solvent fraction and a fraction that is mostly extracted seeds and/or sprouts. Finally, a fraction containing the desired glucosinolates and isothiocyanates is recovered. *See Exh. 2A (the '567 patent), col. 22, ll. 22-32, 60-61; see also Exh. 7, ¶¶ 31-33.* This recovered fraction is the "extract."

Claim 15 of the '895 patent, and claims 10, 13, 15-24 and 26 of the '770 patent, are directed to methods of making a food product that includes substantially similar "extracting" steps as the claims of the '567 patent discussed above. *Exh. 1A (the '895 patent) at col. 22, ll. 48-50; Exhibit 5A (the '770 patent) at col. 22, line 37-col. 24, line 8.* Accordingly, the term "extract" in those claims is amenable to the same construction discussed above.

Claims 1, 2, 5, 6-10, and 12 of the '122 patent similarly support Plaintiffs' proposed construction of "extract." Claim 1 of the '122 patent recites a "non-toxic solvent *extract* of a crucifer seed or cruciferous sprout," where the crucifer seed or cruciferous sprout is exposed to a non-toxic solvent. *Exh. 3A (the '122 patent), col. 21, ll. 55-60* (emphasis added).

Claims 2, 5, 6-8, and 12 are dependent from Claim 1 of the '122 patent. Claim 2 specifies what solvent is employed in producing the extract of Claim 1. *Exh. 3A (the '122 patent), col. 21, ll. 61-64.* Claim 5 specifies that the extract is dried, cooled, frozen, or freeze-dried. *Exh. 3A (the '122 patent), col. 22, ll. 4-5.* Claims 6-8 are directed to examples of food products that comprise the extract. *Exh. 3A (the '122 patent), col. 22, ll. 6-11.* Claim 12 is

directed to additional food products comprising the extract. *Exh. 3A (the '122 patent), col. 22, ll. 27-34.* Claims 9 and 10 (which depends from Claim 9) are directed to pills and tablets comprising the extract. *Exh. 3A (the '122 patent), col. 22, ll. 12-19.* Thus, on its face, Claim 1 of the '122 patent conveys that an extract results from the manipulation of crucifer seeds and/or cruciferous sprouts by exposure to non-toxic solvents. The dependent claims of the '122 patent provide greater specificity regarding the form and characteristics of the extract. Further, when considered together with the claims of the '567 patent, it is clear that the "extract" must be that fraction which exists after manipulation of a crucifer seed or cruciferous sprout that contains the greatest amount of the desired glucosinolates and isothiocyanates.

2. The Specification

Plaintiffs' proposed construction of "extract" is confirmed by the common specification of the asserted patents. It explains:

> This invention relates to *a dietary approach* to reducing the level of carcinogens in animals and their cells and thereby reducing the risk of developing cancer. In particular, this invention relates to the production and consumption of *foods* which are rich in cancer chemoprotective compounds. . . . This invention relates to *food sources* which are extremely rich in compounds that induce the activity of Phase 2 enzymes, without inducing biologically significant activities of those Phase 1 enzymes that activate carcinogens.

See, e.g., Exh. 1A (the '895 patent), col. 1, ll. 15-26 (emphases added). The claimed inventions, therefore, have a dietary aspect, including providing food sources that are rich in compounds that induce the activity of Phase 2 enzymes. *See Exh. 7, ¶ 36.*

The common specification further provides:

> Inducer potential or Phase 2 enzyme-inducing potential is a measure of the combined amounts of inducer activity in plant tissue provided by isothiocyanates, plus glucosinolates that can be converted by myrosinase to isothiocyanates. Glucosinolates are not themselves inducers of mammalian Phase 2 enzymes, whereas isothiocyanates are inducers.

Exh. 1A (the '895 patent), col. 6, l. 65-col. 7, l. 3. In other words, within the dietary approach taken by the inventors to provide chemoprotectors (1) isothiocyanates are critical because they are Phase 2 enzyme inducers, and (2) glucosinolates are also important because they can be converted by myrosinase into isothiocyanates. *See Exh. 7, ¶ 37*.

The common specification of the asserted patents also offers the following explanation:

> Non-toxic solvent *extracts* according to the invention are useful as *healthful* infusions or soups. Non-toxic or easily removable solvents useful for extraction according to the present invention include water, liquid carbon dioxide or ethanol, among others. . . . *The extract can be ingested directly, or can be further treated*. . . . It can be mixed with a crucifer vegetable which contains an active myrosinase enzyme. This will accomplish a rapid conversion of the glucosinolates to isothiocyanates, prior to ingestion.

Exh. 1A (the '895 patent), col. 11, ll. 18-34 (emphasis added). This passage confirms that a non-toxic solvent "extract" may be "ingested directly" or as part of a food product, and that in all events the "extract" must be rich with beneficial Phase 2 enzyme inducers and/or their precursors. *See also Exh. 7, ¶¶ 38-40*.

3. Extrinsic Evidence

Plaintiffs' expert, Edward M. Sybert, whose *curriculum vitae* is included in Exhibit 7, has more than forty years of technical experience studying and employing techniques for bioprocessing, from laboratory to production scale, and is at minimum someone skilled in the art for purposes of the asserted patents. Mr. Sybert reviewed, among other things, the claims, specifications, and prosecution histories of asserted patents (*see Exh. 7, ¶¶ 18-19*),[5] and he confirms Plaintiffs' proposed construction of "extract."

In Mr. Sybert's opinion, Claims 9 and 18 of the '567 patent and Claims 1, 2, 5-10, and 12 of the '122 patent are particularly relevant in construing "extract" in that they convey that

[5] Mr. Sybert reviewed the prosecution histories and found that nothing in them conflicted with what is conveyed by the claims and the specification. *Exh. 7, ¶¶ 41-42*.

"cruciferous sprouts and/or seeds are manipulated by exposing them to a solvent in such a way that two or more fractions are produced, including one that contains glucosinolates and isothiocyanates. The fraction containing a high concentration of glucosinolates and isothiocyanates is then recovered." *Exh. 7, ¶¶ 32-35.*

In addition, Mr. Sybert opines that the common specification of the asserted patents conveys to one of ordinary skill at the time of the invention that the extracts of the invention are ingestible and healthy and contain beneficial amounts of Phase 2 enzyme inducers due to the manipulation that occurred with the starting cruciferous material. *Exh. 7, ¶¶ 37-40.*

Defendant's own pre-litigation conduct also confirms Plaintiffs' proposed construction. Exhibit 14 is a manufacturing flow chart and product data sheet for a product previously produced by Defendant called SGS™ 100 "broccoli seed extract." *Exh. A; see also Exh. B.* That flow chart depicts an extraction process where broccoli seeds are exposed to a non-toxic solvent (liquid or "supercritical" CO_2). The products of the extraction process are (1) a fraction rich in glucosinolates and isothiocyanates, which also contains much of the solids in the original seeds; and (2) a fraction containing mostly broccoli seed oil. *See Exh. B; see also Exh. 7 at ¶ 43.* The SGS™ 100 "broccoli seed extract," as described in this document, contains "30 mg of glucoraphinin" which "when consumed daily, serves to boost protective enzymes and enhance liver detoxification." *Exh. A; see also Exh. B.* Thus, in this document, Defendant uses the term "extract" to refer to the fraction from the extraction process that contains the greatest amount of beneficial Phase 2 enzyme inducers and/or their precursors.

In addition, Defendant incorporated SGS™ 100 into a product called Vitalica®, a dietary supplement containing SGS™ (sulforaphane glucosinolate). The package label for the Vitalica® product states that the product contains "[p]atented cruciferous seed *extract*." *Exh. C* (emphasis

added). That label states that "SGS glucosinolate activates the body's natural detoxification and antioxidant enzymes, protecting cells from free radical damage." *Id.*[6] Here again, Defendant's pre-litigation use of the term "extract" to refer to the fraction from an extraction process which contains the greatest amount of beneficial Phase 2 enzyme inducers and/or their precursors, admits a meaning consistent with the construction proposed by Plaintiffs.

4. Defendant's Proposed Construction is Improper

Defendant's proposed construction of "extract" is "material removed by an extraction process wherein a solvent removes the material from the seed and the extract can contain both the removed material and the solvent." This construction cannot be sustained because it fails to consider the patent as a whole, taking into account the patent's complete description of the invention. *See Phillips*, 415 F.3d at 1312-13.

Most particularly, Defendant's proposed construction ignores the language of the asserted claims. The claims require that the "extract" result from the manipulation of a crucifer seed or cruciferous sprout **and** be the portion or fraction of the manipulation that contains beneficial Phase 2 enzyme inducers and/or their precursors. Defendant's proposed construction, however, of Claim 1 of the '122 patent – which recites "A non-toxic solvent extract of a crucifer seed or cruciferous sprout" – would cover extracts that contain little or no glucosinolates and isothiocyanates, as Dr. Ziegler confirmed. *See Exh. 12, p. 42, ll. 3-17.* Such a proposed construction runs completely contrary to the stated goal of the inventors, which is to deliver, not to discard, the beneficial Phase 2 enzyme inducers and/or their precursors. Accordingly, Defendant's proposal would be contrary to settled law. *See Renishaw*, 158 F.3d at 1250.

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[6] Defendant has since changed the labels for the Vitalica® product to refer to "broccoli seed raffinate" rather than extract, but the product has not changed. *Compare Exh. C with Exh. D.*

Defendant's attempt to divine a limitation on "extract" from the prosecution history of the '770 patent is meritless. The material cited by Defendant does not suggest a limitation of any kind, and certainly not the requisite "clear and unmistakable disavowal of scope during prosecution." *See, e.g., Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 38 F.3d 1123, 1136 (Fed. Cir. 2006). Instead, the cited material supports Plaintiffs' proposed construction. In the exchange cited by Defendant, the prior art ("Jones") taught the removal of glucosinolates from the seeds, leaving behind a "protein concentrate." *Exh. 5F at 5-F41* (*Amendment and Reply Under 37 C.F.R. § 1.111 filed October 22, 2002, p. 4).* Addressing Jones, the inventors stated that "the method of Jones comprises entirely different steps and results in a completely different product [*i.e.*, a product lacking glucosinolates] than the presently claimed method." *Id.* This exchange confirms the examiner's acceptance of the inventors' express intention that that "extract" would contain beneficial amounts of Phase 2 enzyme inducers and/or their precursors.

Nor would the opinion of Dr. Ziegler, Defendant's purported expert, compel a contrary conclusion. First, Dr. Ziegler is not an expert nor one skilled in the art relative to the inventions of the asserted patents.[7] Second, Dr. Ziegler's consideration of relevant materials, admittedly,

[7] For example, Dr. Ziegler characterized himself "an expert on chocolate," has never done any research on cruciferous seeds or sprouts, and although this case pertains to solid-liquid extractions, most of Dr. Ziegler's "personal experience with extraction processes are for liquid-liquid systems." *Exh. 12, pp. 7, ll.10-15; 18, ll. 7-14; 67, ll. 4-6.*

was cursory at best.[8] Third, Dr. Ziegler's opinion is based largely on extrinsic evidence, in the form of treatises, rather than on the patents and their prosecution histories.[9]

For all of these reasons, Plaintiffs submit that their proposed construction of the term "extract" is proper and should be adopted by the Court.

C. "Food Product"

The goal of the claimed inventions is to provide chemoprotective Phase 2 enzyme inducers using a dietary approach. Accordingly, each claimed "food product" must provide the beneficial Phase 2 enzyme inducers and/or their precursors. Thus, Plaintiffs propose that the claim term "**food product**" should be construed to mean:

> **any ingestible substance containing beneficial amounts of Phase 2 enzyme inducers and/or their precursors.**

1. The Asserted Claims Language

In the asserted claims, the term "food product" is found in Claims 14 and 15 of the '895 patent; Claims 9, 16, and 18 of the '567 patent; Claims 6, 7, 8, and 12 of the '122 patent; Claims

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[8] Dr. Ziegler testified at deposition that he "based most of [his] opinion on the reading of [only the] original ['895] patent," and he only "skimmed over the rest." *Exh. 12, p. 10, ll. 1-3; p. 14, ll. 3-6.* Consequently, although the asserted patents cover more than methods, Dr. Ziegler erroneously assumed that the asserted patents pertain only to methods. *Exh. 12, p. 10, ll. 16-17; p. 11, ll. 1-9; p. 17, ll. 8-15.* In fact, he spent only about six hours preparing his initial expert report. *Exh. 12, p. 86, ll. 20-22.*

[9] Dr. Ziegler's expert report confirms that his opinion is based principally on extrinsic evidence: he discusses the definition of the term "extract" as used by several treatises (*Exh. 8, pp. 2-3*) before opining that the use of the term in the patents is consistent with those extrinsic sources (*Exh. 8, p. 3*). His rebuttal report is likewise primarily concerned with the use of the term "extract" in treatises (*Exh. 9, pp. 2-3),* noting explicitly that he is "not aware of any technical reference or treatise that uses the terms extract, extracting, or extraction as does Mr. Sybert…" *Id. at 4.*

1 and 2 of the '018 patent; and Claims 10, 13, 15-24, and 26 of the '770 patent.[10] The language of these claims supports Plaintiffs' proposed construction.

Claim 10 of the '770 patent claims "A method of making a ***food product***" by:

[1] "extracting glucosinolates and isothiocyanates from cruciferous plant tissue,

[2] "recovering said glucosinolates and isothiocyanates and

[3] "adding said glucosinolates and isothiocyanates to food; . . . ."

Exh. 5A (the '770 patent), col. 22, ll. 37-45 (emphasis added). This claimed method, thus, plainly specifies that glucosinolates and isothiocyanates *(i.e.*, beneficial Phase 2 enzyme inducers or their precursors) are added to food, resulting in the "food product."

Claim 19 of the '770 patent, which depends from Claim 10, specifies that the "*food product* is selected from the group consisting of a bread, a drink, a soup, a salad, a sandwich and a cereal." *Exh. 5A (the '770 patent), col. 23, ll. 1-3* (emphasis added). Notably, while Claim 19 sets forth specific examples of ingestible food items, Claim 10 is not constrained to specific examples, conveying that a "food product" may be anything properly consumed or ingested. *See Phillips*, 415 F.3d at 1314; *see also Exh. 7, ¶ 46*.

Claims 1 and 6-8 of the '122 patent, read in combination, are also helpful in construing "food product." Each of Claims 6-8, which depend from Claim 1, is directed to a "food product" that comprises the "extract" of Claim 1. *Exh. 3A (the '122 patent), col. 22, ll. 6-11*. Because, according to the patents, an "extract" contains beneficial amounts of Phase 2 enzyme inducers and/or their precursors, so, too, must a "food product" that is comprised of such an "extract." *See Exh. 7, ¶¶ 47-48*.

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[10] *See Exh. 1A (the '895 patent), col. 22, ll. 40-48; Exh. 2A (the '567 patent), col. 22, ll. 22-32, 53-55, 60-61; Exh. 3A (the '122 patent), col. 22, ll. 6-11, 27-34; Exh. 4A (the '018 patent), col. 21, ll. 46-56; Exh. 5A, col. 22, ll. 37-46, 51-52, l. 54-col. 24, l. 8.*

In addition, Claim 8 of the '122 patent lists additional representative "food products," including "food supplements, drinks, shakes, baked goods, teas, soups, cereals, pills, tablets, sandwiches, and granolas." *Exh. 3A (the '122 patent), col. 22, ll. 8-11.* Thus, a claimed "food product" includes not only conventional foods, but also food supplements, pills, and tablets. All of these are ingestible, even though they may not typically be thought of as foods.

Further, Claim 14 of the '895 patent, which is directed to another "method of preparing a food product," establishes that a "food product" also includes a cruciferous seed itself, as well as other "edible ingredients, that include glucosinolates. Claim 14 reads:

> [a] method of preparing a food product comprising introducing cruciferous seeds, . . . and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates, into *another* edible ingredient.

Exh. 1A (the '895 patent), col. 22, ll. 40-47 (emphasis added).

Taken together, these claims establish that a "food product" is any type of food (*see* Claim 10 of the '770 patent), including without limitation bread, drinks, soups, salads, sandwiches, cereals, food supplements, shakes, baked goods, teas, and granolas (*see* Claim 19 of the '770 patent and Claim 8 of the '122 patent), as well as pills and tablets (*see* Claim 8 of the '122 patent), and even any ingestible substance, such as cruciferous seeds (*see* Claim 14 of the '895 patent). Moreover, and regardless of the type of ingestible substance, a "food product" must include beneficial amounts of Phase 2 enzyme inducers, isothiocyantes, and/or their precursors, glucosinolates (*see* Claim 14 of the '895 patent and Claim 10 of the '770 patent).

2. The Specification

Plaintiffs' proposed construction of "food product" is further supported by the common specification of the asserted patents.

First, the proposed construction is consistent with the objectives of the inventions, as stated in the common specification.[11] The inventions seek to provide, using a dietary approach, chemoprotective Phase 2 enzyme inducers and/or their precursors. Specifically, the specification provides that one object of the invention is to "provide food products and food additives that are rich in cancer chemoprotective compounds." *See, e.g., Exh. 1A (the '895 patent), col. 2, ll. 37-39.* Other listed objects include "provid[ing] food products which contain substantial quantities of Phase 2 enzyme-inducers [that] are essentially free of Phase I enzyme-inducers." *See, e.g., Exh. 1A (the '895 patent), col. 2, ll. 40-43.* Many additional references in the specification recite "food product"[12] and convey to one of ordinary skill in the art that a "food product" contains substantial quantities of Phase 2 enzyme-inducers. *See Exh. 7, ¶¶ 49-50.*

Second, three key passages in the specification establish the appropriate construction of "food product." These are:

> **A *food product* is any ingestible preparation containing the sprouts of the instant invention, or extracts or preparations made from these sprouts, which are capable of delivering Phase 2 inducers to the mammal ingesting the food product.** The *food product* can be freshly prepared such as salads, drinks or sandwiches containing sprouts of the instant invention. Alternatively, the *food product* containing sprouts of the instant invention can be dried, cooked, boiled, lyophilized or baked. Breads, teas, soups, cereals, pills and tablets, are among the vast number of different *food products* contemplated." *Exh. 1A (the '895 patent), col. 6, ll. 27-37* (emphases added).
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> *****
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> ***Seeds*, as well as sprouts[,] have been found to be extremely rich in inducer potential. Thus it is within the scope of the invention to use crucifer**

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[11] "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Research Plastics v. Federal Packing,* 421 F.3d 1290, 1295 (Fed. Cir. 2005) (quoting *Renishaw,* 158 F.3d at 1250).

[12] *See, e.g., Exh. 1A (the '895 patent), Abstract; col. 2, l. 36-col. 5, l. 67; col. 6, l. 26-31; col. 11, ll. 50-60.*

> ***seeds* in *food products*.** *Exh. 1A (the '895 patent), col. 11, ll. 37-39* (emphases added)
>
> *****
>
> ***Food products* of the instant invention may include sprouts, *seeds* or *extracts* of sprouts or *seeds* taken from one or more different crucifer genera, species, varieties, subvarieties or cultivars.** It has been found that genetically distinct crucifers produce chemically distinct Phase 2 enzyme-inducers. Different Phase 2 enzyme-inducers detoxify chemically distinct carcinogens at different rates. **Accordingly, *food products* composed of genetically distinct crucifer sprouts or *seeds*, or *extracts* or preparations made from these sprouts or *seeds*, with detoxify a broader range of carcinogens.** *See, e.g., Exh. 1A (the '895 patent), col. 11, ll. 50-60* (emphases added).

These passages make clear that a "food product" is not limited to an ingestible substance that must contain sprouts or sprout extracts, as Defendant contends (*see* below). Instead, because seeds are also "extremely rich in [Phase 2 enzyme] inducer potential," seeds and seed extracts can be food products. These passages also convey that a "food product" is *any* ingestible substance that contains the beneficial Phase 2 enzyme inducers and/or their precursors – ranging from salads to drinks to breads to pills. *See Exh. 7, ¶¶ 51-55.*

3. Extrinsic Evidence

Mr. Sybert's expert opinion also supports Plaintiffs' construction of "food product." [13] As he did when he considered "extract," Mr. Sybert examined how "food product" would be interpreted by one of skill in the art at the time of the invention. *See Exh. 7, ¶¶ 24-28, 45-57.*

Mr. Sybert found Claims 10 and 19 of the '770 patent particularly relevant in construing "food product" because those claims conveyed that a "food product" "includes items that are consumed or ingested, such as bread, drinks, soups, salad, sandwiches, and cereals." *See Exh. 7, ¶ 46.* Mr. Sybert also found Claims 1, 2, 5-10, and 12 of the '122 patent relevant because those claims convey that "cruciferous sprouts and/or seeds are manipulated such that a fraction

[13] Defendant's proposed expert, Dr. Ziegler, did not consider the construction of "food product" and rendered no opinion on it.

containing glucosinolates and isothiocyanates results, and that fraction may be used in *food products*." *See Exh. 7, ¶¶ 47-48* (emphasis added).

Mr. Sybert also focused on the asserted patents as a whole, concluding that the specification conveys that a "food product" has "special attributes, *i.e.*, substantial quantities of Phase 2 enzyme-inducers." *See Exh. 7, ¶ 50.* Mr. Sybert also concluded that several passages in the specification, when read together, convey that a "food product" is "something that is ingested by a mammal" that can take many forms and that "may be produced from crucifer seeds, including from extracts of crucifer seeds." *See Exh. 7, ¶¶ 51-55.*

4. Defendant's Proposed Construction Is Unsupportable

Defendant's proposed construction of "food product" is:

> any ingestible preparation containing sprouts identified and having the characteristics described in the '895 patent specification, at col. 10, l. 28 - col. 11, l. 17, or extracts or preparations made from these sprouts, which are capable of delivering Phase 2 inducers to the mammal ingesting the food product. A food product may include other compounds, including seeds or extracts of seeds, in addition to the sprouts or extracts of preparations from sprouts.

Because this construction would *require* the presence of sprouts or sprout extracts in an ingestible for it to be a "food product" it is too narrow and unsupportable. Significantly, it ignores the goal of the claimed inventions, and fails to take into account a full consideration of the patents' claim language and specification. *See Research Plastics,* 421 F.3d at 1295 (citing *Renishaw*, 158 F.3d at 1250).

In particular, Defendant limits its consideration to only one part of the specification, while ignoring other parts that reflect the inventors' intentions, to say nothing of the relevant claim language discussed above. *See supra at Sections 1.A., II.C.1., II.C.2.* Thus, Defendant would rely only upon the language in the "Definitions" subsection of the "Detailed Description" which provides that "A food product is any ingestible preparation containing the sprouts of the

instant invention, or extracts or preparations made from these sprouts, which are capable of delivering Phase 2 inducers to the mammal ingesting the food product." Yet, it would ignore the very next subsection, which explains that

> Seeds, as well as sprouts have been found to be extremely rich in inducer potential. Thus it is within the scope of the invention to use crucifer seeds in food products.
>
> * * *
>
> Food products of the instant invention may include **sprouts, seeds, or extracts of sprouts or seeds** taken from one or more different crucifer genera, species, varieties, subvarieties, or cultivars.

Exhibit 1A (the '895 patent), col. 11, ll. 37-60. Such selective reading of the patent is improper as a matter of law. *Markman,* 517 U.S. at 389 ("[A claim] term can be defined only in a way that comports with the instrument as a whole."); *Phillips,* 415 F.3d at 1321 ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent.").

It is also legally infirm for Defendant to ignore the meaning of the term "food product" as established by the patents' claim language. *Philips,* 415 F.3d at 1314-1315. As discussed above, *see supra at Section ll.C.1.*, the claim language is expansive with respect to the types of foods that comprise a "food product." *See Exh. 5A (the '770 patent), col. 22, ll. 37-45, col. 23, ll. 1-3; Exh. 3A (the '122 patent), col. 22, ll. 6-11.* Moreover, Claim 9 of the '122 patent, on its face belies Defendant's proposed construction because it expressly states that the "pill or tablet" – which are food products (*see* '122 patent, Claim 8) – is not only a cruciferous sprout, but also a cruciferous seed.

Nor can Defendant limit the definition of "food product" using the prosecution history of the '895 patent. Defendant contends that a "food product" cannot be a seed or seed extract alone. The portions of the '895 patent prosecution history cited by Defendant, however, merely

relate to the Examiner's concern that certain prior art references may have taught broccoli sprouts as a food product. None of the cited references related to seeds. Moreover, in response to the Examiner's inquiry, the inventors clarified that the primary reference (a Japanese patent application) was mistranslated and did not teach sprouts, nor did the secondary references. *Exh. 1C at 1-C37-40 (Amendment and Request for Reconsideration Under 37 C.F.R. §1.111 filed March 17, 1997, pp. 2-5).* The same is true with respect to Defendant's attempt to rely upon the file histories of the '567 patent and U.S. Patent No. 5,968,505 (the latter of which is not even being asserted in this case). For these reasons, Defendant's attempted reliance on prosecution histories is misplaced. *See, e.g., Purdue,* 38 F.3d at 1136.

For all of these reasons, Plaintiffs submit that their proposed construction of "food product" should be adopted by the Court.

III. DEFENDANT'S REMAINING CONSTRUCTIONS ARE UNNECESSARY

In addition to "extract" and "food product," Defendant asks the Court to construe eighteen additional claim terms. *See Appendix A.* Construction of these additional terms is unnecessary, however, because the meaning of the other terms is readily apparent.

For example, "human food product" is simply a "food product" suitable for human consumption. "Cruciferous" and "crucifer" are synonyms and mean plants of the family *Cruciferae*. *Exh. 1A (the '895 patent), col. 10, ll. 32-34.* Similarly, "plant tissue" is tissue of any plant. *See Exh. 5A (the '770 patent), col. 22, ll. 37-58.* To construe these terms, one need only apply widely-accepted meanings of commonly-understood words. *Phillips,* 415 F.3d at 1314.

Most of Defendant's other proposed additional terms simply build upon the meaning of "extract:" (i) "extracting glucosinolates and isothiocyanates from cruciferous sprouts . . . or from cruciferous seeds . . . ," (ii) "removing the extracted sprouts, seeds, or a combination thereof from said solvent," (iii) "recovering the extracted glucosinolates and isothiocyanates,"

(iv) ”drying said extracted glucosinolates and isothiocyanates;” (v) “An extract prepared according to the method of any one of claims 9, 16, or 17;” (vi) “A non-toxic solvent extract of crucifer seed or cruciferous sprout;” (vii) “To extract said seed or sprout;” (viii) “said extract is dried, cooled, frozen, or freeze-dried;” (ix) “the extract;” and (x) “extract of said seed.” These terms simply require reference to the meaning of “extract” and to the commonly-understood modifiers or variations of the term.

The remaining “terms” for which Caudill seeks special construction are “recovering said glucosinolates and isothiocyanates;” “homogenizing said plant tissue with said non-toxic solvent;” “at a temperature sufficient to inactivate myrosinase enzyme activity;” and “non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates.” The meaning of the “recovering” and “homogenizing” limitations can be determined with reference to the asserted patents and do not require special construction, involving only “the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. The meaning of the “temperature” limitation proposed by Defendant is simply incorrect, as the patents clearly state that myrosinase is inactive at different temperatures depending on the experimental conditions. *Exh. 1A (‘895 patent), col. 9, ll. 7-13; col. 21, ll. 22-26* (less than 50°C); *col. 11, ll. 22-24* (hot or boiling water). And, finally, “non-toxic levels of indole glucosinolates . . .” can be readily understood. The plain meaning of non-toxic is not poisonous; thus, as explained by the ‘895 patent, the levels called for by this phrase are those that neither activate Phase I enzymes nor result in goiter. *See, e.g., ‘895 patent, col. 11, ll. 8-16; col. 1, ll. 22-26.*

If the Court determines that any of these additional terms should be construed, Plaintiffs' proposed constructions – which consider the asserted patents as a whole and stay true to the inventors' goal of delivering chemoprotective compounds – should be adopted.

Conclusion

For the foregoing reasons, Plaintiffs respectfully submit that their proposed claim constructions for the terms "extract" and "food product" should be adopted, and that the additional claim terms for which Defendant seeks construction should be treated, if at all, as set forth in Appendix A of the parties' Joint Claim Construction and Prehearing Statement.

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Respectfully submitted,

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